

1633 '99 SEP 21 P1:51

TO: FDA, Docket No. 98N-1230, 96P-0418 and 97P-0197
FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852
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FROM: Danny R. Hughes, President
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The following comments are submitted on the behalf of the National Egg Regulatory Officials (NERO). The membership of NERO consists of 35 State Department of Agriculture officials involved in shell egg and egg product regulations and programs. Examples of areas regulated by members include refrigeration of shell eggs, enforcement of quality standards, egg container labeling, record keeping for handlers of shell eggs, sanitation standards for shell egg processing plants and third party monitoring of Egg Quality Assurance Plans. Many members have cooperative agreements with USDA/AMS and USDA/FSIS for inspections conducted under the Egg Products Inspection Act and for the voluntary grading of shell eggs. The primary goal of the NERO organization is to promote uniform state, local and federal regulations concerning shell eggs and egg products that provide effective consumer protection in the areas of egg safety, quality and labeling.

Labeling

NERO strongly supports safe handling labeling requirements for shell eggs, however, we feel FDA's proposed rule could be more effective. We feel the labeling statement FDA has proposed is too lengthy with the most important information at the end of the statement. We are concerned about the length for two reasons. One is the probability of consumers reading the entire statement. As proposed, the labeling places more emphasis on warning of the risk than it does on safe handling.

The second concern with the proposed label is the amount of room available on a carton to display the information. FDA indicates in the federal register that the effects of the proposal on the States has been examined. We agree with the assessment that consistent safe handling instructions are necessary and will not preempt more stringent State regulations. However, the requirements as proposed will have a significant impact on the industry in complying with both State and Federal requirements. NERO recently conducted a survey of states to determine State Egg Law labeling requirements. Forty states responded to this survey. Based on this survey of State Egg Law labeling requirements (survey results are attached), 100 % of the respondents have labeling requirements. Many states have specific requirements for location - principal display

panel or information panel, type size and/or specific wording. For example, several states have specific requirements for refrigeration labeling. Some states require this information to be on the principal display panel while others require specific language that is not included in FDA's proposed safe handling instruction. To comply with both federal and state law, the industry would either have to place the safe handling instruction on the principal display panel or put a refrigeration statement on the principal display panel and the safe handling instruction on the information panel. Legislative changes at the State level would be necessary to reduce the regulatory burden on the industry. Additionally, the States require other information such as grade and size, registration number to identify the packer, date of pack, and expiration dates that are not required by FDA's Fair Packaging and Labeling. This information is important to the consumer and the States in the enforcement of State Egg Laws. The amount of space on cartons is limited on one dozen cartons. The industry is now using six egg and eight egg cartons that have even more limited space. The more concise FDA makes the required safe handling instruction, the easier it will be for industry to comply with State and Federal requirements.

We would recommend a statement such as "Keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly". This statement contains all of the information necessary to inform consumers how to avoid food borne illness, is easier for consumers to read and would take considerably less room on the carton. The statement emphasizes positive action consumers can take to prevent food borne illness.

The FDA proposed rule also indicates eggs destined for food service could have the safe handling instructions on invoices or bills of lading. In our experience, invoices and bills of lading are not in the possession of the persons handling the receiving and preparation of the eggs. Additionally, the majority of salmonella enteritidis outbreaks have been traced back to a combination of egg contamination and mishandling of the product at the food service level. The majority of the eggs shipped to food service establishments are in 15 dozen or 30 dozen cases that have ample room for additional labeling. As there is adequate room on these cases, inclusion of the food service safe handling instructions developed by the American Egg Board along with a warning statement that failure to follow these guidelines could result in food borne illness would be more effective in reducing the mishandling of eggs at food service establishments. These instructions include guidelines for refrigeration, handling and preparation and would be readily visible to the food handlers if they were on the container.

We agree with FDA's tentative conclusion that the States and localities would be able to enforce the safe handling instructions labeling requirements. As we have already discussed, of the 40 States responding to our labeling survey, 100% are already enforcing some type of labeling requirements for shell eggs. As our membership is already involved in enforcement of labeling requirements, a cooperative enforcement effort with FDA would be very effective.

Refrigeration

FDA's proposed rule that would require shell eggs to be held at 45°F is an excellent step towards creating a uniform national standard that will reduce the risk of bacterial growth in shell eggs. The inclusion of food banks and flea markets under this rule will close existing gaps. The lack of a requirement for nest run eggs is a gap in the refrigeration of shell eggs from farm to table. FSIS and/or FDA should consider a national requirement for the refrigeration of shell eggs prior to processing and packaging.

The federal register notice indicates FDA has tentatively concluded to allow states and localities to enforce the refrigeration regulation along with FDA. We agree that FDA, State and local enforcement could be very effective. In many States, responsibility for shell egg refrigeration resides in the State Department of Agriculture or is shared jointly by a State Department of Agriculture and a State Health Department. The State Egg Inspection programs generally enforce refrigeration violations that are specific to shell eggs. Enforcement actions vary from state to state with some removing unrefrigerated eggs from sale and some issuing fines to retailers and/or food service for failure to refrigerate. The majority of these States already have a structure in place for administrative hearings. State Health Departments generally enforce potentially hazardous food refrigeration violations, but do not handle issues directly related to shell eggs. As the State Department of Agriculture Egg Inspection programs are directly related to eggs, the documentation of temperature violations may be useful to FDA's enforcement efforts.

We would recommend FDA contact both types of agencies concerning enforcement of shell egg refrigeration. NERO represents 35 of the State Department of Agriculture Egg Inspection programs and could serve as a starting point for FDA to discuss joint enforcement efforts. Before we can specifically comment on "how State, local and Federal food safety authorities can best interface to ensure effective and efficient implementation and enforcement of food safety standards" we need additional information on the type of cooperation FDA is seeking. There are several options that would provide effective and efficient implementation and enforcement through cooperation. State egg inspection programs or other appropriate state or local programs could continue to monitor retail and food service facilities for temperature violations and report repeated violations to FDA for additional action. This method would be very cost effective. Another option would be for State and local programs to report temperature violations to FDA through a national database. The development of a national database would be very expensive and would not necessarily yield better compliance. FDA training of State and local officials would be effective regardless of the type of cooperative enforcement that is developed. Our membership has found past FDA training sessions to be extremely beneficial.

NERO is concerned about the proposal to destroy or divert to pasteurization any eggs found held at temperatures above 45°F. One of our concerns is the inconsistency between FSIS' regulations and FDA's proposed rule. If eggs are found to be held at temperatures above 45°F in locations covered by FSIS' regulations, it is a facility violation and the product is not retained. Under FDA's rule, the product would be destroyed or diverted to pasteurization. There is a limited

number of egg products plants in the United States. The direct shipment of eggs from retailers and food service facilities to egg products plants is not feasible. Retailers and food service facilities would not be able to divert product for pasteurization without returning it to the processor. This means the eggs would almost have to be destroyed. The proposed regulation indicates all eggs found to be out of compliance for refrigeration would be destroyed or diverted. As proposed, this regulation does not provide for eggs that are out of compliance for limited amounts of time. State Egg Law inspectors often find eggs that were recently delivered but have not been placed in the coolers. The allowance of a reasonable amount of time to place eggs in the cooler after delivery would not compromise the safety of the eggs. We would also recommend the use of civil penalties to encourage compliance by retailers and food service establishments to minimize the destruction of eggs.

The small entity analysis indicates approximately 25,400 small entities will be affected by the refrigeration provision of the proposed rule. Although the information in the register is specific in how FDA determined the number of small entities, it is not specific in how it determined the number of those small entities are not currently refrigerating shell eggs. The attached survey done by NERO on State refrigeration requirements may be useful in determining the number of small entities not refrigerating. It would be reasonable to assume that the small entities in the States that have a 45 °F or less temperature requirement are already in compliance with FDA's proposed rule.

**ATTACHMENT I
NATIONAL EGG REGULATORY OFFICIALS
SURVEY OF STATE LABELING REQUIREMENTS FOR ONE DOZEN CARTONS
AS OF SEPTEMBER 14, 1999**

STATE	GRADE	SIZE	NAME & ADDRESS Packer Distributor	REGISTRATION # State issued EPIA USDA	DATE OF PACK Julienne Other	DATE - EXP. SELL BY, USE BY	NUTRITIONAL LABELING	REFRIGERATION STATEMENT	QUANTITY STATEMENT	IDENTITY STATEMENT
USDA - Officially Graded Product	PDP	PDP	P or D/PDP or IP	U	IP	NR	IP	NR	PDP	PDP
FDA (FAIR PACKAGING & LABELING)										
ALABAMA	3/16"/PDP	3/16"/PDP	IP	S,E or U/PDP or IP	1/8"	NR	IP	IP	PDP	PDP
ALASKA										
ARIZONA	1/4"	1/4"	P or D	NR	NR	S/24day	NR	NR	NR	NR
ARKANSAS	3/8" PDP or IP	3/8" PDP or IP	R	S, U or E	R	NR	NR	R	R	NR
CALIFORNIA	1/4"/IP or PDP	1/4"/IP or PDP	R	S,U or E	J	S/30 day	NR	IP or PDP	R	R
COLORADO										
CONNECTICUT										
DELAWARE	3/8"	3/8"	P or D	NR	NR	NR	NR	NR	3/8"	R
FLORIDA	R	R	R	NR	R	NR	R	NR	NR	NR
GEORGIA	1/4"	1/4"	R	S or U	R	E, U or S	NR	NR	1/4"	R
HAWAII	3/16"/PDP	3/16"/PDP	3/16"	NR	NR	NR	NR	PDP	3/16"/PDP	R

KEY: R = REQUIRED - specific height and/or location not required or unknown; NR = NOT REQUIRED; PDP = PRINCIPAL DISPLAY PANEL; IP = INFORMATION PANEL

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IDAHO										
ILLINOIS	1/8"/PDP	1/8"/PDP	P or D/1/8"	S, E, U or O	J	E or S/30 or 15	NR	R	1/8"/PDP	1/8"/PDP
INDIANA	R	R	R	S,E or U	R	E/30 day	NR	R	NR	NR
IOWA	1/4"	1/4"	1/4"	S or U	R	NR	NR	NR	NR	R
KANSAS	3/8"/PDP	3/8"/PDP	R	S or U	R	NR	NR	NR	NR	NR
KENTUCKY	1/4"	1/4"	R	S,E or U	R	E,S or U/30 day	IP	R	1/4"	NR
LOUISIANA	R	R	R	S	R	NR	NR	R	R	R
MAINE	R	R	P or D	NR	NR	NR	NR	NR	R	R
MARYLAND	3/8"/ PDP	3/8"/ PDP	P or D 1/16"/PDP OR IP	S,E or U 1/16"/PDP OR IP	1/16" PDP OR IP	NR	NR	1/16"/PDP	3/16" PDP	1/16"/PDP
MASSACHUSETTS										
MICHIGAN	1/16"	1/16"	R	NR	NR	S/90 days	NR	NR	PDP	R
MINNESOTA										
MISSISSIPPI										

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MISSOURI	3/16"	3/16"	3/16"	S,E or U	R	NR	NR	NR	NR	NR
MONTANA										
NEBRASKA	R	R	R	E	R	NR	NR	NR	3/8"	R
NEVADA	1/4 to 1/2"	1/4 to 1/2"	R	NR	NR	NR	NR	NR	R	NR
NEW HAMPSHIRE	R	R	NR	NR	NR	NR	NR	NR	NR	NR
NEW JERSEY	3/8"/IP	3/8"/IP	PDP	NR	NR	NR	NR	NR	IP	R
NEW MEXICO	R	R	R	NR	NR	NR	NR	NR	R	NR
NEW YORK	3/8"/PDP	3/8"/PDP	1/16"/PDP	S,E or U	NR	NR	R	NR	1/16"/IP or PDP	3/8"/PDP
NORTH CAROLINA	3/8"/PDP or IP	3/8"/PDP or IP	P	NR	NR	NR	NR	NR	3/8"	R
NORTH DAKOTA										
OHIO	R	R	NR	NR	R	NR	NR	NR	R	NR
OKLAHOMA	PDP	PDP	R	E,S,U, or O	R	NR	NR	NR	R	R
OREGON	1/4"/PDP	1/4"/PDP	R	NR	NR	S	NR	NR	R	R
PENNSYLVANIA	3/16"	3/16"	R	NR	R	NR	NR	R	NR	R

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RHODE ISLAND	R	R	NR	NR	NR	NR	NR	R	R	R
SOUTH CAROLINA	5/16"/PDP	5/16"/PDP	1/8"/D or P	Cases Only	NR	NR	NR	NR	R	R
SOUTH DAKOTA	R	R	NR	S,E or O	R	E	NR	R	R	R
TENNESSEE	PDP	PDP	R	NR	R	NR	NR	NR	PDP	R
TEXAS	PDP	PDP	R	S or U	NR	NR	NR	NR	PDP	NR
UTAH	R	R	R	NR	R	NR	NR	R	PDP	R
VERMONT	PDP	PDP	R	E or U	NR	NR	NR	NR	R	R
VIRGINIA	PDP*	PDP	R	NR	NR	NR	NR	NR	PDP	R
WASHINGTON	1/8"/PDP	1/8"/PDP	IP	S, E or U	NR	NR	NR	R	PDP	NR
WEST VIRGINIA	R	R	R	E or U	NR	R	NR	R	R	R
WISCONSIN	PDP	PDP	R	S, E or U	R	R	R	R	PDP	R
WYOMING										

*1/2 as high as tallest letter in the word eggs.

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STATUS OF STATE REFRIGERATION LAWS - APRIL, 1998

STATE	ENFORCEMENT AGENCY	YEAR ENACTED	ENFORCEMENT TYPE	TEMPERATURES					
				PRE PROCESSING	POST PROCESSING	WHOLESALE	RETAIL	FOOD SERVICE	TRANSPORTATION
ALABAMA	1	1991	1	NONE	45° A	45° A	45° A	45° A	45° A
ALASKA	NONE								
ARIZONA	1	1958	3	60° A	60° A	60° A	60° A	60° A	60° A
ARKANSAS	1,2	1993	4	NONE	45° A	45° A	45° A	45° A	45° A
CALIFORNIA									
COLORADO	1,2	1997	1,2,3,4	NONE	NONE	41° A	41° A	41° A	45° A
CONNECTICUT	1	1990	1	NONE	45° A	45° A	45° A	45° A	45° A (RESTAURANTS ONLY)
DELAWARE	1	1968	1,4	NONE	NONE	60° A	60° A	NONE	NONE
	2	Unknown	1	NONE	NONE	NONE	NONE	41° I	41° I
FLORIDA	1	1997	4	NONE	45° A	45° A	45° A	45° A	45° A
GEORGIA	1	1995	4	NONE	45° A	45° A	45° A	45° A	45° A
HAWAII	1	1994		NONE	60° A	NONE	NONE	NONE	NONE
	2	1994		NONE	NONE	45° A	45° A	45° A	45° A
IDAHO									
ILLINOIS	1,2		1,2,3	60° A	45° A	45° A	45° A	45° A	45° A
INDIANA	1,2	1983	1	NONE	45° A	45° A	45° A	45° A	NONE

Key

Enforcement Agency

1 = State Department of Agriculture
2 = State Public Health Agency
3 = Other

Enforcement Type

1 = Removal from sale
2 = Destruction
3 = Fines
4 = Other

Temperature

Indicate degrees in Fahrenheit
A = Ambient
I = Internal

Information Compiled by:

National Egg Regulatory Officials
50 Harry S. Truman Parkway
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410-841-5769 FAX 410-841-2765
Contact: Deanna Baldwin

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STATE	ENFORCEMENT AGENCY	YEAR ENACTED	ENFORCEMENT TYPE	TEMPERATURES					
				PRE PROCESSING	POST PROCESSING	WHOLESALE	RETAIL	FOOD SERVICE	TRANSPORTATION
IOWA									
KANSAS									
KENTUCKY	2		2	NONE	NONE	45°A	45°A	45°A	NONE
LOUISIANA	1	1993	2,4	NONE	45°A	45°A	45°A	45°A	45°A
MAINE	NONE								
MARYLAND	1,2	1993	1,2,4	NONE	45°A	45°A	45°A	45°A	45°A
MASSACHUSETTS									
MICHIGAN									
MINNESOTA	1,2	1991	1,2	50°A	45°A	45°A	45°A	45°I	50°A
MISSISSIPPI	1	1997	4	NONE	60°A	NONE	45°A	HEALTH DEPT	NONE
MISSOURI	1		4	NONE	NONE	60°A	60°A	NONE	NONE
MONTANA									
NEBRASKA									
NEVADA	2	UNKNOWN	1,2	NONE	NONE	NONE	NONE	50°A	NONE
NEW HAMPSHIRE	2	PLANS ON ADOPTING 1998		NONE	NONE	NONE	45°A	45°A	NONE
NEW JERSEY									

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NEW MEXICO									
NEW YORK	1,2			NONE	NONE	NONE	45°A		
NORTH CAROLINA	1	1991	1	60°A	45°A	45°A	45°A	45°A	45°A
NORTH DAKOTA									
OHIO	1	1996	1,3	NONE	45°A	45°A	45°A	45°A	45°A
OKLAHOMA	1	N/A	1,4	NONE	USDA	NONE	NONE	NONE	NONE
OREGON	1,2	1993	1,2	NONE	45°I	45°I	45°I	45°I	45°I
PENNSYLVANIA	1,2	1991	1	55°A	45°A	45°A	45°I	45°I	45°A
RHODE ISLAND	2	1995	2	NONE	41°	41°A	41°A	41°A	41°A
SOUTH CAROLINA	2			NONE	NONE	45°A	45°A	45°A	45°A
SOUTH DAKOTA	1			NONE	>45°A	>45°A	45°A	45°A	50°I
TENNESSEE	1	N/A	NONE	NONE	NONE	NONE	NONE	NONE	NONE
TEXAS	1,2	1997	1	60°A	45°A	45°A	45°A		45°A
UTAH	1,2	1991	1,2,3,4	55°A	45°A	45°A	45°A	41°I	NONE
VERMONT									
VIRGINIA	1,2	1968	1,2,3	NONE	60°A	60°A	60°A	60°A	60°A

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				PRE PROCESSING	POST PROCESSING	WHOLESALE	RETAIL	FOOD SERVICE	TRANSPORTATION
WASHINGTON	1	1991, 1995	1,2,3	55° A	45° A	45° A	45° A	NONE	45° A
	2	1992					45° I	45° I	
WEST VIRGINIA	1	1965	1,2	NONE	45° A	45° A	45° A	45° A	45° A
	2						45°	45°	
WISCONSIN	1,2	1996	4	60° A	45° A	40° A	40° A	40° A	45° A
WYOMING									

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HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CROSS REFERENCE SHEET

Docket Number/Item Code: 98N-1230/C645

See Docket Number/Item Code: 97P-0197/C646
96P-0418/C645

Dept of Agriculture
Harry S. Truman Pkwy
Apo 112, MD 21401



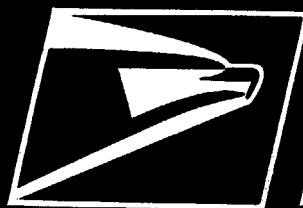
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20852

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21842
SEP 18 '99
AMOUNT

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**PRIORITY
MAIL**

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DO USE:

1. COMPLETE ADDRESS LABEL AREA

Type or print required return address and addressee information in customer block (white area) or on label (if provided).

2. PAYMENT METHOD

Affix postage or meter strip to area indicated in upper right hand corner.

FDA/Dockets Management Branch (HFA 305)
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